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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES L. MAGNESS and
SHAWN P. IADONATO

Appeal 2009-014777
Application 09/707,576
Technology Center 1600

Decided: May 27, 2010

Before ERIC GRIMES, FRANCISCO C. PRATS, and STEPHEN WALSH, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for identifying drug targets, which the Examiner has rejected for nonenablement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that the "current state-of-the-art in genomics and genetics involves the use of these technologies to understand the genetic basis of disease" (Spec. 1: 8-9) and that "the prevailing paradigm is that a disease gene is a handle onto a biochemical pathway that will ultimately lead to a new drug target" (*id.* at 1: 24-25). The Specification "describes an alternative to the historical use of genomics in the drug development process. . . . Rather than using genomics to understand why some people become sick, the present invention describes a process to determine the genetic influences that allow people to remain healthy, even under conditions where they are expected to be sick." (*Id.* at 5: 2-6.)

Claims 1-10, 14-26, 28, 31-44, and 46-55 are on appeal. Claim 1 is representative and reads as follows:

1. A computer implemented method for the identification of a drug target associated with a selected biological condition, comprising:

using a computer to analyze stored data related to medical histories of a population;

using a computer to analyze stored data related to medical test results for the population; and

based on computer analysis of the data related to the medical histories and the data related to the medical test results, classifying the population into at least two phenotypic sub populations defined as

at risk and affected (ARA), whose members have ever been affected by the selected biological condition, and

at risk and unaffected (ARU), whose members ought to be affected by the selected biological condition at the present time based on a risk analysis, but are unaffected by the selected biological condition at the present time;

performing a computer analysis of genetic data from the ARA sub population and the ARU sub population to identify genetic variations therebetween;

displaying the data for a user; and

using data related to the identified genetic variations between the ARA sub population and the ARU sub population to identify the drug target associated with the selected biological condition.

Issue

The Examiner has rejected all of the claims on appeal under 35 U.S.C. § 112, second paragraph, as nonenabled.[1] The Examiner finds that a number of the factors set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), weigh in favor of nonenablement (Ans. 4-7) and concludes that undue experimentation would be required to practice the claimed method to identify a drug target for a given biological condition (*id.* at 8).

Appellants contend that "the Examiner has failed to adequately consider the originally filed application as well as the expert affidavits previously filed" (Appeal Br. 13) and that "the testimony in the Affidavits confirms that the presently pending claims are fully enabled by the instant application" (*id.* at 15).

The issue presented is: Is the Examiner's conclusion that the claimed method would require undue experimentation supported by a preponderance of the evidence of record?

Findings of Fact

1. The Examiner finds that the Specification "sets forth steps that are taken to analyze a population and define affected status, risk factors, and the

[1] As issues on appeal, Appellants also include the Examiner's refusal to withdraw the finality of the Office Action mailed May 16, 2007 (Appeal Br. 11-12) and denial of entry of the amendment filed Nov. 16, 2007 (*id.* at 15). Those issues, however, can be reviewed only by way of petition. See MPEP § 1002.02(c).

characterization of ARA, ARU, and URU [unknown risk, unaffected] phenotypes" (Ans. 5).

2. The Examiner acknowledges that the disclosed method has been used "to identify a gene associated with Hepatitis C" (*id.*).[2]

3. The Examiner finds that the "gene associated with hepatitis C is not an actual drug target for treatment of hepatitis C. Identification of a gene associated with Hepatitis C[ ] does not enable the identification of a drug target." (*Id.*)

4. The Examiner finds that the "disclosure does not provide any examples wherein a drug target is identified" (*id.*).

5. The Examiner finds that "even where the genetic disease is 'known' . . . , in many instances, the etiology of a disease is such that the 'target' for treatment is not the gene itself. For example, it is well known that the BRCA gene is used to identify those at risk of breast cancer however, the drug target for the disease is not the BRCA gene." (*Id.*)

6. The Examiner finds that "[i]t is well known in the art how to define ARA and ARU populations and depending on the disease, it may be possible to find a genetic difference between two defined populations. However, . . . [t]he identification of a gene is not the same as identification of a drug target for the disease." (*Id.* at 6.)

7. The Examiner finds that the prior art does not teach methods of identifying a drug target associated with a biological condition "through data

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[2] The Examiner states that "the specification provides a working example of how to identify a gene associated with Hepatitis C" (Ans. 5) but, as we understand it, the Examiner is referring to evidence provided in Appellants' declarations; the Specification does not provide any working examples.

related to genetic variations between ARA and ARU subpopulations, wherein no prior knowledge of a relationship between said target and said biological condition is available" (*id.*).

8. The Examiner finds that the level of skill in the relevant art is high (*id.*).

9. The Examiner finds that "it is well known in the art that down- or up-regulation of expression of a protein (gene product) may cause a disorder" but that changes in protein expression can result from a number of different causes (*id.*). The Examiner finds that any of those underlying causes "may, in fact, be the 'target' which needs to be addressed for appropriate treatment of the disease or disorder. . . . [T]he disease itself may still be treated; perhaps by administration of higher levels of the protein; however, even if the protein were to be considered a 'drug,' the 'drug' is not directed to a 'target.'" (*Id.* at 6-7.)

10. The Examiner finds that the claims are broad (*id.* at 7).

11. Appellants have submitted Declarations under 37 C.F.R. § 1.132 of Shawn Iadonato (filed Feb. 22, 2007), Richard M. Myers (filed Dec. 18, 2006), and Cammie Lesser (filed Dec. 18, 2006).[3]

12. Dr. Iadonato testified that a drug for treating hepatitis C "was developed by following the methods as explicitly described in the present patent application" (Iadonato Declaration, ¶ 5).

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[3] Appellants also filed a Rule 132 Declaration of Shawn Iadonato on Dec. 18, 2006, but the Declaration filed Feb. 22, 2007 incorporates the substance of the earlier Declaration . We will therefore only refer to the later Declaration .

13. Dr. Iadonato testified that the hepatitis C drug was developed by identifying mutations associated with "at risk and unaffected" patients (*id.* at ¶ 7), and that the "laboratory work supporting the computational genetic analysis was conducted using a single sequencing instrument and approximately one full-time-equivalent laboratory technician" (*id.* at ¶ 8).

14. Dr. Iadonato testified that "[b]y following the methods described in this application, we identified a drug target (the mutated gene OAS1) initially in about six months and a drug in three years from start to preclinical drug candidate. A single cycle of data input, review and analysis according to the invention led directly to this drug discovery." (*Id.* at ¶ 10.)

15. Dr. Myers testified that "much of the genetics work (that the examiner appears to believe not enabled in the application) is routine" (Myers Declaration, ¶ 4).

16. Dr. Myers testified that, in his opinion, "anyone of ordinary skill in the field of molecular genetics would have a comparable level of familiarity and expertise" to his own (*id.* at ¶ 5).

17. Dr. Myers testified that "it is possible and routine to identify a mutation without knowledge of the underlying disease mechanism, and to determine whether that mutation corresponds to phenotypic characteristics of a subpopulation, such as the 'at risk unaffected'" (*id.* at ¶ 6).

18. Dr. Myers testified that, in his opinion, "identifying 'at risk unaffected' and 'at risk affected' populations, and obtaining biological samples, such as blood samples, is routine and need not be time-consuming" (*id.* at ¶ 7).

19. Dr. Myers testified that "[u]sing well-known methods of sequence analysis and mutation identification, it is entirely feasible and within

ordinary skill in this art to identify a genetic difference that correlates with the affected versus unaffected phenotype" (*id.*).

20. Dr. Myers testified that "[o]ne of ordinary skill will be familiar with the input of data from human samples and the methods and search parameters for identifying genetic differences between two samples" (*id.* at ¶ 11).

21. Dr. Lesser testified that "it is possible and routine to identify a mutation without knowledge of the underlying disease mechanism, and to determine whether that mutation corresponds to phenotypic characteristics of a population such as the ARU group" (Lesser Declaration, ¶ 4).

22. Dr. Lesser testified that, in her opinion, "identifying 'at risk unaffected' and 'at risk affected' populations, and obtaining biological samples, such as blood samples, is routine and need not be time-consuming" (*id.* at ¶ 5).

23. Dr. Lesser testified that "[u]sing well-known methods of sequence analysis, mutation identification and statistical genetics, it is entirely feasible and within ordinary skill in this art to identify a genetic difference that correlates with the affected versus unaffected phenotype"" (*id.* at ¶ 7).

24. Dr. Lesser testified that "[m]any of the risk analyses and genetic comparisons outlined by the present methods are also amenable to computer automation" (*id.* at ¶ 9).

25. Dr. Lesser testified as follows:

> I am a person of ordinary skill in this art. It is within my ability to understand and follow the claimed methods. For any disease in which the phenotype is related to a genetic difference, I would expect the claimed methods to allow someone of my

> skill level to discover that difference, and to correlate it with a gene-specific effect, such as a protein modification.

(*Id.* at ¶ 11.)

Principles of Law

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

"[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Analysis

The Examiner has identified factors that, in his view, support a conclusion under a *Wands* analysis that the claims are not supported by an enabling disclosure. Appellants have provided declaratory evidence in response to the Examiner's rejection. Appellants have provided evidence that

- a drug for treating hepatitis C was developed following the methods disclosed in the present application (FF 12);

• the gene leading to the hepatitis C drug was identified in six months on the basis of laboratory work using a single sequencing machine and one full-time laboratory technician (FF 14);

• two people who consider themselves to have ordinary skill in the art (FFs 16, 25) testified that it is routine to identify ARA and ARU populations and obtain biological samples for analysis (FFs 18, 22);

• two people who consider themselves to have ordinary skill in the art testified that it is routine to identify a mutation and correlate it to an "at risk, unaffected" subpopulation (FFs 17, 19, 21); and

• people of ordinary skill in this art are familiar with computer-based methods of analyzing genetic data (FF 20).

The Examiner has not pointed to any evidence of record showing that the statements in Appellants' Declarations are factually wrong or that the conclusions of Appellants' Declarants would not be shared by a worker of ordinary skill in this field. We therefore conclude that the Examiner's rejection is not supported by a preponderance of the evidence of record.

Conclusion of Law

The Examiner's conclusion that the claimed method would require undue experimentation is not supported by a preponderance of the evidence of record.

SUMMARY

We reverse the rejection of claims 1-10, 14-26, 28, 31-44, and 46-55 under 35 U.S.C. § 112, first paragraph, for nonenablement.

REVERSED

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